REMARKS

The Final Office Action mailed May 14, 2008 has been received and reviewed. In the Final Office Action the Examiner has:

(1) maintained the rejection of claims 1, 14-15, and 17 under 35 U.S.C. § 112, first paragraph, for failure to meet the enablement requirement; and

(2) rejected claims 1, 5-6, 14, and 35 under 35 U.S.C. § 102(b) as being anticipated by any one of U.S. Patent Nos. 5,623,056, 5,601,828, or 5,242,687 to Tykocinski et al.

In connection with the present Response, claims 18-26 have been cancelled, claims 1, 5, and 6 have been amended, and new claims 40-53 have been added. No new subject matter has been added in connection with the amendments. Upon entry of the above amendments, claims 1, 5-6, 14-15, 17, and 40-53 remain pending in the present application.

In view of the foregoing changes and the following remarks, Applicants respectfully request reconsideration of the claims.

35 U.S.C. § 112

With respect to item (1), the Examiner has maintained the rejection of claims 1, 14-15, and 17 for failure to meet the enablement requirement under 35 U.S.C. § 112, first paragraph. In particular, the Examiner has noted that although independent claim 1 is directed to a method for inhibiting an adaptive T cell response, at no point in the claim is there a step that includes exposure of such cells to an allogenic tissue, which could mount an adaptive T cell response.

Independent claim 1 has been amended, as provided above, and is now directed to a method for producing an allograft cell designed to inhibit development of an adaptive T cell response. Since claim 1 is now directed to a method of producing an allograft cell rather than a method for inhibiting an adaptive T cell response, the step of exposing cells to an allogenic tissue, as required by the Examiner, is no longer needed. Accordingly,

Applicants submit that claim 1 and its dependent claims, claims 14, 15 and 17, have now satisfied the requirement under 35 U.S.C. § 112, first paragraph, and are now in condition for allowance.

35 U.S.C. § 102

With respect to item (2), the Examiner has asserted that claims 1, 5-6, 14-15, and 17 are anticipated by any one of U.S. Patent Nos. 5,623,056, 5,601,828, or 5,242,687 to Tykocinski et al.

Independent claim 1, now directed to a method for producing an allograft cell designed to inhibit development of an adaptive T cell response, has been amended to recite, among other things, the step of providing a non-immunogenic expression vector encoding a CD8 polypeptide.

Likewise, independent claim 5, directed to a method for inhibiting the development of an adaptive T cell responses, and claim 6, directed to a method for extending the survival of an allograft in a recipient, have been amended to now recite, among other things, the step of contacting *ex vivo* a non-immunogenic expression vector encoding a CD8 polypeptide with allograft cells.

Support for the use of a non-immunogenic expression vector can be found throughout the present application, including paragraphs 134 and 148 of the published application. In particular, such an expression vector is deprived of viral genes or has had the viral coding sequences removed.

In contrast, Tykocinski et al. fail to teach, in any of their three patents, the use of a non-immunogenic expression vector in connection with the production of an allograft cell designed to inhibit development of an adaptive T cell response, in connection with the inhibition of the development of an adaptive T cell response, or in connection with the extension of the survival of an allograft in a recipient.

The Examiner has noted, in the office action, that Tykocinski et al. generally disclose the use of vectors to transform the cells, or that at least it is inherent that a vector is used when performing transformation. However, Applicants note that nowhere within

any of the Tykocinski references is there any teaching or disclosure in connection with the use of a non-immunogenic expression vector in the manner set forth in independent claims 1, 5 and 6.

Accordingly, Applicants submit that claims 1, 5 and 6 cannot be anticipated by Tykocinski et al., as disclosed in any of the three references.

Claims 14, 15 and 17 are dependent from claims 1, 5 and 6. It thus follows that these claims are also not anticipated by Tykocinski et al., as disclosed in any of the three references.

New Claims 40 - 53

New claims 40-53 have been added to set forth certain novel features of the present invention. Support for the new claims may be found throughout Applicants specification and drawings as filed. No new matter has been added.

Independent claim 40 is directed to a composition for transplantation into a recipient. The composition, as recited, comprises a donor cell having an alloantigen on a surface of the donor cell. The donor cell, in an embodiment, can be conditioned with a non-immunogenic expression vector encoding a CD8 polypeptide consisting of all or a functional portion of a CD8 α-chain resulting in expression of the CD8 α-chain on the surface of the donor cell. Support for this claim may be found, for example, in paragraphs 12, 14-15, and 158 of the present application as published, as well as in Example 3.

Dependent claim 41 is directed to a composition wherein the donor cell is a cell found in a tissue or organ at risk of a graft versus host disease immune response. Support for this claim may be found, for example, in paragraph 16 of the present application as published.

Dependent claim 42 is directed to a composition wherein the tissue or the organ is one of a liver, a skin or an intestinal tract. Support for this claim may be found, for example, in paragraph 16 of the present application as published.

Dependent claim 43 is directed to a composition wherein the donor cell can be present as a single entity, or can be part of a larger collection of cells. Support for this claim may be found, for example, in paragraph 62 of the present application as published.

Dependent claim 44 is directed to a composition wherein the larger collection of cells is one of a cell culture, a tissue, an organ, or an organ system. Support for this claim may be found, for example, in paragraph 62 of the present application as published.

Dependent claim 45 is directed to a composition wherein the tissue is an epithelial tissue. Support for this claim may be found, for example, in paragraph 62 of the present application as published.

Dependent claim 46 is directed to a composition wherein the organ is one of a heart, a lung or a liver. Support for this claim may be found, for example, in paragraph 62 of the present application as published.

Dependent claim 47 is directed to a composition wherein the organ system is a nervous system. Support for this claim may be found, for example, in paragraph 62 of the present application as published.

Dependent claim 48 is directed to a composition wherein transplantation into the recipient effectively and specifically inhibits an immune response directed against the composition. Support for this claim may be found, for example, in claim 5 as originally filed, and in paragraph 24 of the present application as published.

Dependent claim 49 is directed to a composition wherein the donor cell is a donor cell of an allograft transplant tissue. Support for this claim may be found, for example, in paragraph 160 of the present application as published.

Dependent claim 50 is directed to a composition wherein transplantation of the allograft transplant tissue into the recipient prolongs a survival time of the allograft transplant tissue. Support for this claim may be found, for example, in claim 6 as originally filed, and in paragraph 17 of the present application as published.

Dependent claim 51 is directed to a composition wherein transplantation of the allograft transplant tissue into the recipient induces stable immunological tolerance to the allograft transplant tissue. Support for this claim may be found, for example, in paragraphs 17 and 18 of the present application as published.

Dependent claim 52 is directed to a composition wherein the CD8 α-chain is a human CD8 α-chain. Support for this claim may be found, for example, in paragraphs 14-18 of the present application as published.

Dependent claim 53 is directed to a composition wherein the CD8 α-chain consists of a CD8 α-chain extracellular domain and a transmembrane domain. Support for this claim may be found, for example, in paragraph 19 of the present application as published.

Conclusion

Accordingly, Applicants submit that pending claims 1, 5-6, 14-15, 17, and 40-53 are in condition for allowance. Withdrawal of the pending rejections, and early and favorable reconsideration are respectfully solicited. In the event that a telephone conversation would further prosecute and/or expedite allowance, the Examiner is invited to contact the undersigned at (617) 310-6000.

Applicant requests a three (3) month extension of time in connection with the filing of this RCE and Response, and authorizes the Examiner to charge an amount of $960 ($555.00 for 3 Month Extension of Time, $405.00 for RCE filing fee) to Deposit Account No. 50-2678, Reference 108674-010201, to cover the requisite fee.

Applicants do not believe that any additional fees are required in connection with this Response. However, should any fees be required for timely consideration of the present application, Applicants hereby petition for same and request that the fees required for timely consideration of this application be charged to Deposit Account No. 50-2678, Reference 108674-010201.

Respectfully submitted,

/Chinh H. Pham/
Chinh H. Pham
Registration No. 39,329

Greenberg Traurig, LLP
One International Place
Boston, Massachusetts 02110
Tel.: 617-310-6000
Fax: 617-310-6001